Remarks

Claims 16, 18, 20-27, 29, 30, 35, and 37-50 are pending and at issue in the present application, claims 1-15, 17, 19, 28, 31-34, and 36 having been cancelled, and claims 37-50 being newly presented by this amendment.

Claims 16 and 35 stand rejected under 35 U.S.C. §112 ¶ 2 for being "vague and indefinite."

Claims 16, 18, 20-27, 29, 30, and 35 stand rejected as obvious over Malackowski (US 2003/0093103) in view of Van Der Brug (US 5954648) and DiGioia (US 6205411).

Support for Amendments

Claim 16 has been amended to recite that the multi-step surgical procedure comprises a first sequence of steps. Support for this amendment may be found at least at FIGS. 1 and 3 and in the specification at paragraphs 0002, 0016, and 0018 (all paragraph numbers are from the published application), which describe a surgical procedure as having a "specialized workflow" and a "multi-step procedure" that includes "current," "prior," and "future" steps. A person of ordinary skill would understand that the multi-step procedure has a number of steps that are preferably to be completed in a particular sequence, i.e., a "first sequence." Claim 16 has been further amended to recite that the computer navigation system comprises means for identifying a current step within the multi-step surgical procedure. Support for this amendment may be found at least at FIG. 3, reference number 150, and associated description in the specification. Claim 16 has also been amended to recite that the computer navigation system comprises means for analyzing steps of the surgical procedure including a step other than the current step or an immediately subsequent step in the first sequence. Support for this amendment may be found at least at FIG. 3 and in paragraph 0018, which describes a routine that can be implemented by a computer (described in paragraphs 0019 and 0020), wherein the block 156 determines if the tool is acceptable for a prior step in the procedure, which is a step other than the current step or an immediately subsequent step in the first sequence. Claim 16 has been further amended to recite that the computer navigation system comprises means for identifying the consequent step as the first step analyzed for which the component is acceptable. Support for these amendments may be found at least at FIG. 3 and in paragraph 0018, which describes a subroutine for determining the appropriate consequent step wherein the subroutine identifies the

consequent step as being the first step analyzed in the subroutine for which the component is deemed acceptable.

Claim 35 has been amended to recite a method comprising the step of identifying a location of the component within a field of tracking of the computer navigation system. Support for this amendment may be found at least in paragraph 0016, which describes that the system will identify the surgical instruments brought within the view of the surgical navigation system, in paragraph 0017, which describes that a tracking device is located by the navigation system, in paragraph 0020, which describes introducing a surgical tool into the view of the surgical navigation system, and in paragraph 0021, which describes that the block 302 of FIG. 5 will determine the location of the tool within the surgical field. A person of skill in the art would understand at least these descriptions to teach that the computer navigation system identifies a location of the component within a field of tracking of the computer navigation system. Support for the remaining amendments to claim 35 may be found at least as indicated with respect to the amendments to claim 16 and will not be repeated for the sake of brevity.

New claim 37 recites a method performed by a computer navigation system of determining and displaying a consequent step of a surgical procedure comprising a first sequence of steps, the method comprising identifying a current step of the surgical procedure, identifying a component being tracked by the computer navigation system that is to be utilized in at least one step of the surgical procedure, analyzing steps of the surgical procedure including a step other than the current step or an immediately subsequent step in the first sequence, identifying the consequent step as the first step analyzed for which the component is acceptable, and automatically jumping to the consequent step and displaying a representation related to the consequent step on a display unit. Support for new claim 37 may be found at least in the locations of the original disclosure pointed out above with respect to claims 16 and 35, and will not be repeated here for the sake of brevity.

Support for the remaining newly presented claims 38-50 may be found at least in the claims as originally filed and in the sections of the specification identified above with respect to claims 16 and 35.

Traversal of Rejections Under 35 U.S.C. § 112, ¶2

It is argued in the Office action that claims 16 and 35 are vague and indefinite because the

recitation of selecting a consequent step from a group of steps including at least the particular step, the prior step, and the future step may not read on a situation wherein the particular step is either the first step or the last step of the procedure. These rejections are traversed. There is no legal requirement for a recited claim element to read on every possible permutation. Rather, a claim element is sufficiently definite if it reads on at least one possible permutation described in the specification in a manner reasonably sufficient to provide notice to a person of ordinary skill as to what is being claimed as the invention. However, because claims 16 and 35 have been amended to remove the claim language objected to in the Office action, the rejections are moot and should be withdrawn.

Traversal of Rejections Under 35 U.S.C. § 103 Over Malackowski, Van Der Brug, and DiGioia

The rejections of claims 16, 18, 20-27, 29, 30, and 35 over Malackowski in view of Van Der Brug and DiGioia are traversed.

None of the applied references discloses or suggests a computer navigation system for implementing a multi-step surgical procedure that comprises a first sequence of steps, as recited in claim 16, wherein the computer navigation system comprises means for analyzing steps of the surgical procedure including a step other than the current step or an immediately subsequent step in the first sequence, and means for identifying the consequent step as the first step analyzed for which the component is acceptable.

Further, none of the applied references discloses or suggests a method performed by a computer navigation system of determining and displaying a consequent step of a procedure comprising a first sequence of steps, as recited in claim 35, including analyzing whether the component is acceptable for use in steps of the surgical procedure including a step other than the current step or an immediately subsequent step in the first sequence, and determining the consequent step based on the location, the identity of the component, and the identity of the current step.

Further still, none of the applied references discloses or suggests a method performed by a computer navigation system of determining and displaying a consequent step of a surgical procedure comprising a first sequence of steps, as recited in claim 37, including analyzing steps of the surgical procedure including a step other than the current step or an immediately subsequent step in the first

sequence and identifying the consequent step as the first step analyzed for which the component is acceptable.

Rather, the applied references at most suggest that, based on an identity of a surgical tool, a computer navigation system could select a consequent step in a multi-step surgical procedure from at most either the current step or an immediately subsequent step in the sequence of the procedure. However, the applied references do not suggest that the consequent step selected based on the identity of the surgical tool could be selected from a group including a step other than the current step or the immediately subsequent step in the sequence of the procedure.

In particular, Malackowski discloses a surgical navigation system that implements a multi-step surgical procedure and reacts to identifying information from a surgical tool by displaying a warning and/or preventing actuation of the next step if the tool has unsatisfactory parameters for the next step in a predetermined sequence of surgical steps. Malackowski in relevant part at most suggests that the surgical navigation system selects the appropriate response based on what the current step and the immediately next step in the multi-step surgical procedure are supposed to be. However, Malackowski does not disclose that the surgical navigation system reacts by selecting a consequent step from a group of steps that include a step other than the current step or an immediately subsequent step in the sequence of the multi-step procedure.

Van Der Brug and DiGioia do not supply the deficiency pointed out in Malackowski. Van Der Brug discloses a surgical navigation system that, in relevant part, discloses only that the surgical navigation system tracks the location of a surgical instrument within a surgical field. However, Van Der Brug does not disclose that the surgical navigation system selects any steps of a multi-step procedure based on an identity of the surgical tool. DiGioia discloses a computer-assisted surgery planner and intra-operative guidance system including a navigation system that works progressively through a pre-defined sequence of pre-operative planning steps and intra-operative surgery steps. DiGioia does not disclose or suggest that the navigation system would ascertain an identity of a surgical tool and select a consequent surgical step that is a step other than the current step or an immediately subsequent step in the sequence of the multi-step procedure based on the identity of the surgical tool.

It is alleged in the Office action that Malackowski discloses that "the computer navigation

system selects the consequent step from a group of steps of the multi-step surgical procedure including . . . a prior step. . . (see at least Malackowski [0154-0158])." O.A., at page 4. However, paragraphs 0154-0158 describe a procedure wherein at each step of the surgical procedure, the surgical navigation software determines only if it is appropriate to advance to the next step of the procedure. This portion of Malackowski does not disclose or suggest that the computer navigation software analyzes whether a tool or component for use in the surgical procedure is acceptable for use in any steps other than the current step or the next step of the procedure. Therefore, this section of Malackowski does not supply the deficiencies identified herein, and the allegation to the contrary in the pending Office action is traversed.

In fact, the invention(s) as claimed variously in the pending claims overcomes deficiencies in the applied references by allowing the surgical navigation system to follow the selections of tools and/or components made by the surgeon during the procedure, for example, without requiring direct intervention with the software by a user, such as on a keyboard or other input device, to re-direct the software to the new step, *even if the consequent step is a step other than the current step or the next step in the procedure*. As explained in the specification, this frees the surgeon to jump to other steps in the procedure by merely introducing a new component into the tracking field of view of the navigation system, and eliminates the need to manually re-set the surgical procedure if the component is to be used in a step other than the current step or the immediately next step. The prior art, however, would require the surgeon or some other operator to manually re-direct the surgical procedure to the desired step of the procedure if the component introduced into the tracking field is not acceptable for use in the current step or the immediate next step of the pre-defined sequence of surgical steps. Such manual intervention required by the prior art can be cumbersome and undesirable in the operating room environment. Therefore, the present invention is a substantial improvement over the prior art of the applied references by eliminating or reducing the need for such direct intervention with the navigation system.

Because the applied references do not disclose or suggest every element of the claims, the applied references do not present a *prima facie* case of obviousness or anticipation, and the pending rejections should be withdrawn.
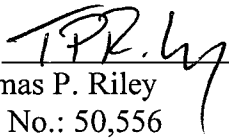
Conclusion

All of the pending rejections having been fully addressed and overcome herein, immediate allowance of the claims at issue is requested.

Should minor new issues be identified that may be addressed telephonically, the examiner is invited to call the undersigned to address such issues.

Respectfully submitted,

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